REMARKS

1. Substance of the Interview

The helpfulness and courtesies extended by the Examiners during the interview of 5 November 2008 are appreciated. During that interview, the discussions focused on the enablement and prior art rejections set forth in the Office Action of May 14, 2008.

With respect to the enablement rejection, Applicant's representative discussed the *Sauter et al.* publication (discussed below) which provides further support for Applicant's claims to prophylactically suppressing type-2 diabetes. It was also discussed that claim 15 might be amended to define that the prophylactic treatment was directed to "a mammal predisposed to type-2 diabetes", noting the discussion of such a treatment in the Specification at page 11, lines 10-13. The prior art rejections were also discussed, specifically noting the differences between type-1 and type-2 diabetes. In this regard, Applicant's representative referred to the publication in Diabetes Care which identifies a number of types of diabetes beyond only type-1 and type-2 diabetes. That publication is further discussed below.

2. Amendments to the Claims

Claim 15 has been amended to specifically define that the prophylactic treatment is to "a mammal predisposed to type-2 diabetes". This amendment is supported by the Specification at page 11, lines 10-13.

3. Enablement Rejection

Claims 15-21 have been rejected under 35 U.S.C. § 112, first paragraph. This rejection is respectfully traversed reconsideration and withdrawal thereof are requested.

In the Office Action the Examiner has indicated that Applicant overcame the enablement rejection in the prior Office Action regarding "the *in vivo* methods" but has maintained the enablement rejection with respect to "prophylactic treatment". First of all, Applicant submits

that the Examiner's rejection is improper because the Examiner has not provided any factual basis to question the objective enablement provided by the Specification. With the prior response Applicant submitted Exhibit 6 and 7 to further evidence the prophylactic treatment by means of the invention. In response, the Examiner has not provided any counter evidence or provided any factual basis to question enablement of Applicant's claims.

Nevertheless, Applicant encloses yet further evidence of enablement in the form of the publication by *Sauter et al.* that describes test results which show that Kineret (the commercially available form of anakinra) is "able to protect from diabetes progression induced by a high-fat diet". (See the last sentence of the introductory section on page 2209) *Sauter et al.* conclude that the test results "show that IL-1Ra improve glucose tolerance, insulin secretion, and insulin sensitivity in C57BL/6J mice feed with HFD (Surwit), serving as an animal model of T2DM" (type-2 diabetes). (See the fourth full sentence of the discussion section beginning on page 2214)

Applicant submits that the Specification as filed fully enables the claims, the Examiner has not provided any objective evidence to question that enablement, and Applicant has, in any event, submitted further evidence to substantiate enablement. Accordingly, the rejection should be withdrawn.

4. Prior Art Rejections

4.1. Claim Rejections – 35 U.S.C. § 102

Claims 15 and 16 have been rejected under 35 U.S.C. § 102(b) over *Thompson et al.* (U.S. Patent 6,159,460). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner basically reasons that "every mammal would be in need" of prophylactically suppressing type-2 diabetes, so "any method of administering the compound for any reason or any population would meet this limitation". Although Applicant does not concede the propriety of the Examiner's reasoning, claim 15 has been amended to define that the prophylactic

treatment is for suppressing type-2 diabetes "in a mammal predisposed to type-2 diabetes". It is believed that this amendment obviates the rejection, so that the rejection under 35 U.S.C. § 102 should be withdrawn.

4.2. Claim Rejections – 35 U.S.C § 103

Claims 15-17 have been rejected under 35 U.S.C. § 103(a) over *Boone et al.* (U.S. Patent 6,294,170) in view of *Thompson et al.* This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Although the Examiner admits that both of the cited references, *Boone et al.* and *Thompson et al.* are silent with respect to any treatment of type-2 diabetes, the Examiner takes the position that the term "insulin diabetes" in both of the references "would encompass type-2 diabetes". Applicant submits that this fundamental position by the Examiner in reading the references is improper and undercuts any rejection of the claims over the prior art.

Applicant submits that the term "insulin diabetes" used in the two cited references would be understood by those skilled in the art to actually refer to type-1 diabetes, and would not be understood to refer to type-2 diabetes.

Type-1 diabetes is often referred to as "insulin-dependent diabetes" and is understood to be an autoimmune disease that results in the permanent destruction of the insulin-producing beta cells of the pancreas. Type-1 diabetes is lethal unless treated with exogenous insulin, such as by injections to replace the missing hormone. Hence the reference of the disease to "insulin dependent".

In complete contrast, type-2 diabetes is often referred to as "non-insulin-dependent diabetes mellitus" (or NIDDM). This condition is a metabolic disease and is primarily characterized by the inability of the cells to response to insulin appropriately. This means that the insulin that is produced by the pancreas cannot connect with fat and muscle cells to permit glucose inside and thereby produce energy. This causes hyperglycemia (high blood glucose) in a patient. To

compensate for this condition, the pancreas produces more insulin, and when this compensatory mechanism fails, type-2 diabetes occurs.

It is therefore submitted that the Examiner's underlying assumption that the term "insulin diabetes" implicitly also includes type-2 diabetes is actually self contradictory and represents a fundamental misunderstanding of diabetes. One skilled in the art would actually understand the term "insulin diabetes" as referring to "insulin dependent diabetes", that is to type-1 diabetes. Such a person would not consider the term to cover type-2 diabetes because a person skilled in the art would understand that type-2 diabetes is otherwise referred to as "non-insulin-dependent" diabetes.

The second position of the Examiner set forth in the Office Action is that "at the time of filing, there are only two types of diabetes: type-1 and type-2". Thus the Examiner reasons that if *Boone et al.* had intended to mean only type-1 diabetes, "he would have likely said disclosed type-1 diabetes". However, this fundamental position is again incorrect and does not properly represent the understanding of those skilled in the art.

In actual fact, at the time of filing of the present application those skilled in the art had identified a large number of different types of diabetes, actually 11 different main types of diabetes and including at least 50 different subtypes. For example, the enclosed "Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus" describes in table 1, page 57, type-1 diabetes, type-2 diabetes and nine other "specific types" of diabetes, such as "genetic defects of beta-cell function", "genetic defects in insulin action", etc.

With this better understanding of the art, Applicant submits that any reference by *Boone* and *Thompson* to "insulin diabetes" would have been understood to be a reference to type-1 diabetes and not a generic reference to type-1, type-2 and any of the other 11 main types of diabetes or 50 different subtypes, nor to a generic term to encompass type-1 and type-2 diabetes.

Since the fundamental basis of the Examiner's interpretation of the prior art has been shown to be incorrect, Applicant submits that the rejection should be withdrawn.

In view of the above, reconsideration and withdrawal of the rejections and allowance of all the claims are requested.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of $1,110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

If the Examiner has any questions concerning this application, the Examiner is requested to contact Leonard R. Svensson, Reg. No. 30,330 at the telephone number of (858) 792-8855. Facsimile communications may be sent to the undersigned at the facsimile number of (858) 792-3785.

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Respectfully submitted,

By _____

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